K013194

OCT 1 0 2001

11. 510(k) SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS

A. Name and Address of Submitter

Company Name and Address:	Biotech Atlantic, Inc. 6 Industrial Way West Eatontown, NJ 07724
Telephone	732-389-4789
FAX:	732-389-3837
Contact Person:	Francis Lee

B. Device Names

Proprietary Name:	UniMark® hCG Combo Pregnancy Test
Common Name:	hCG Pregnancy Test
Classification Name:	Human Chorionic Gonadotropin (hCG) Test System

C. Legally Marketed Device

UniMark® hCG Pregnancy Test, K941090

D. Device Description

UniMark® hCG Combo Pregnancy Test is a chromatographic immunoassay (CIA) for qualitative detection of elevated levels of hCG in serum and urine specimens for the early pregnancy diagnosis. During the test, the specimen is sucked up through the conjugate pad. The hCG in the specimen is captured by the mouse anti-beta hCG antibodies coated on colloidal gold particles. The mixture moves up the membrane by capillary action and is captured by the immobilized goat anti-hCG antibodies at the test zone of the membrane to form an antibody-hCG-gold conjugate complex. An appearance of a purple band in the test zone is the positive result, which indicates presence of hCG and suggests a pregnancy. Absence of this band, on the other hand, displays a negtive result, i.e. no detectable hCG in the specimen. The appearance of the purple band in the control window demonstrates proper performance and validity of the reactive reagent.

E. Intended Use

UniMark® hCG Combo Pregnancy Test (Strip and Device) is for the rapid and qualitative determination of human chorionic gonadotropin (hCG) in serum and urine. It is intended for professional and laboratory use only.

F. Comparison with Predicate Device

The UniMark® hCG Combo Pregnancy Test (Strip and Device) is the same as the UniMark® hCG Pregnancy Test (Strip and Device) with the following exceptions:

- UniMark® hCG Combo Pregnancy Test is intended for use with **both** serum and urine specimens; the UniMark® hCG Pregnancy Test is intended for use with urine specimens **only**

- UniMark® hCG Combo Pregnancy Test contains an additional reagent, normal mouse IgG, in the sample pad to block the nonspecific binding sites of the proteins or antibodies in a serum sample. This minimizes the potential for false positive readings when serum samples are tested.

G. Performance Data

The performance characteristics of the UniMark® Combo hCG Pregnancy Test (Strip and Device) are provided in the package insert, and included sensitivity, accuracy (correlation), specificity, and interference testing with both serum and urine specimens. Sensitivity and accuracy studies were performed in comparison with another combo hCG pregnancy test, the SureStep hCG Combo Pregnancy Test, currently in commercial distribution by Applied Biotech.

H. Conclusions Drawn from the Studies

The conclusions drawn from the performance studies demonstrate that the UniMark® Combo hCG Pregnancy Test is as safe, effective, and performs as well as the legally marketed device to which equivalence is claimed, the UniMark® hCG Pregnancy Test when tested with urine specimens. Further, the sensitivity and accuracy of the UniMark® Combo hCG Pregnancy Test demonstrate that the test is as safe, effective, and performs as well as a legally marketed combo device when tested with both serum and urine specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2001

Mr. Francis Lee
Chief Executive Officer
Biotech Atlantic, Inc.
Meridan Center III
Bay F, 6 Industrial Way West
Eatontown, NJ 07724

Re: k013194
Trade/Device Name: UniMark ® hCG Combo Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: September 24, 2001
Received: September 25, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

UniMark® hCG Combo Pregnancy Test

UniMark® hCG Combo Pregnancy Test (provided either as an individual test strip or as a test strip contained within a plastic test strip holding device) is for the rapid and qualitative determination of human chorionic gonadotropin (hCG) in serum and urine. It is intended for professional and laboratory use only.

It is indicated for use in the early detection of pregnancy.

Please DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____

Per 21 CFR 801.109 (Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013194